32692
Customer Number

Patent
Case No.: 56630US007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	DAVIS, ROBERT A.		
Application No.:	10/821078	Confirmation No.:	1677
Filed:	April 8, 2004	Group Art Unit	3761
Title:	SKIN ANTISEPTIC COMPOSITION DISPENSER AND METHODS OF USE		

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop: Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING OR TRANSMISSION [37 CFR § 1.8(a)]

I hereby certify that this correspondence is being:

☐ deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

☐ transmitted by facsimile on the date shown below to the United States Patent and Trademark Office at 571-273-8300.

☒ transmitted to United States Patent and Trademark Office on the date shown below via the Office electronic filing system.

October 16, 2008 /Chris Johnson/

Date Signed by: Chris Johnson

Dear Sir:

In response to the final action dated July 16, 2008, and prior to filing an appeal brief, a Panel Review of the legal and factual basis of the rejections in the above-identified application is hereby requested. No amendments are being filed with this request. This Pre-Appeal Brief and Request for Review is being filed with a Notice of Appeal.

Fees

☒ Any required fee under 37 CFR § 41.20(b)(2) will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.17 which may be required to Deposit Account No. 13-3723.

☐ Please charge any fees under 37 CFR §§ 37 CFR § 41.20(b)(2) and 1.17 which may be required to Deposit Account No. 13-3723.

☒ Please charge any additional fees associated with the prosecution of this application to Deposit Account No. 13-3723. This authorization includes the fee for any necessary extension of time under 37 CFR § 1.136(a). To the extent any such extension should become necessary, it is hereby requested.

☒ Please credit any overpayment to the same deposit account.

REMARKS

Status of the Claims

The pending claims 58-96 stand rejected.

Review is requested for the following reasons:

Claims 58-96 are rejected under 35 USC 103(a) as being obvious over Dischler (U.S. Patent No. 6,585,693; hereinafter, "Dischler") in view of Richter et al. (U.S. Patent no. 3,396,419; hereinafter, "Richter"). The Examiner indicates that Dischler teaches a device comprising a syringe body 62 and a second blister chamber 42, which houses an injection prep fluid such as alcohol[1]. The Examiner apparently equates the "second blister chamber 42" of Dischler with the skin antiseptic composition dispenser of Applicant's claims. The Examiner asserts that Dischler teaches the same materials (specifically, polypropylene, polyethylene, and polyester) for barrier laminae as those claimed by Applicant and that "Dischler teaches that the container is impermeable to ethylene oxide.[2]" The Examiner indicates that, although Dischler "does not teach that the container is provided with a sterile exterior by exposure to a sterilizing gas.[3]", Richter teaches a cold sterilization process whereby articles are sterilized with ethylene oxide and that it is known in the art to clean and sterilize an antiseptic composition dispenser, e.g. for surgical scrubbing. The Examiner concludes that, "it would be obvious to one of ordinary skill in the art to modify the device of Dischler by providing the container with a sterile exterior by exposure to ethylene oxide (sterilizing gas) as taught by Richter to properly sterilize and clean the dispenser to prevent cross-contamination of a user's skin and the dispenser.[4]"

As a first matter, Applicant respectfully asserts that the Examiner has made several erroneous factual conclusions about the Dischler disclosure. First, Dischler does *not* teach or suggest sterilization other than a sterilizing fluid for injection prep[5]. Second, Dischler does not teach or suggest ethylene oxide or ethylene oxide permeability. In fact, the term

[1] Non-final Office Action dated 07/16/2008; at page 3, first paragraph.
[2] *Ibid*; at page 3, second paragraph
[3] *Ibid*
[4] *Ibid*; at paragraph bridging page 3-4.
[5] U.S. Patent No. 6,585,693; column 2, line 44.

"ethylene oxide" does not appear anywhere in the Dischler disclosure. Third, Dischler does not teach barrier laminae that are inherently substantially impermeable to ethylene oxide, as the Examiner has asserted.[6] Applicant has shown that the ethylene oxide permeability of a container is highly dependent upon the materials and/or construction of the container (see, for example, Tables 1b, 2, and 3 and the following passage from page 37, lines 5-11 of the specification:

> "In general, the data indicates that increasing the barrier film thickness decreases permeability to the sterilant gas ethylene oxide. *There appeared to be differences, however, among materials of the same chemical class.* For example, films 5-10 show significant permeability differences even though they belong to the same chemical class. This may be related to the thickness of the primary barrier layer (fluorinated thermoplastic layer and/or the crystallinity of the primary barrier layer and/or other layers in the construction." (emphasis added)

Applicant has shown how one must *select* the appropriate materials and constructions in order to obtain a container comprising one or more polymeric walls free of metallic layers wherein the container comprises at least one layer that is substantially impermeable to ethylene oxide (as claimed). Dischler does not teach the *selection of materials and/or constructions for ethylene oxide impermeability features* and, therefore, does not anticipate a container that is substantially impermeable to ethylene oxide, as asserted by the Examiner. MPEP 2112 states, "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)." Applicant asserts that at least the feature of a container that is "substantially impermeable to ethylene oxide" is not disclosed or suggested by Dischler. Furthermore, a container that is "substantially impermeable to ethylene oxide" is not disclosed by Richter. Therefore, even if a skilled person was motivated to modify the syringe taught by Dischler with the cold sterilization process taught by Richter, which Applicant does not admit, one could not obtain all of the elements of any one of Applicant's claims 58-96.

As a second matter, Applicant respectfully asserts that the Examiner has made several erroneous factual conclusions about the Richter document. First, the only containers that

[6] Non-final Office Action dated 01/18/2008; at page 2, paragraph 2.

the wraps in which the sponges are preferably packaged[7]. The only reference to sterilizing a "dispenser" found by Applicants in the entire Richter disclosure was in the "Background of the invention"; where Richter disclosed that soap "dispensers are cleaned and **autoclaved** once a day, which is the procedures in the best hospitals.[8]" (emphasis added) Richter teaches the materials for wrapping the sponges "should be of a nature to permit passage of cold sterilizing agents, such as ethylene oxide gas"[9]. Even if Richter suggested sterilizing a *dispenser* containing detergent-impregnated sponges, which Applicant does not admit, there is no teaching or suggestion that the coverings shown for the Richter dispenser (i.e., materials from which the tear strip opening 5 or the outer sheath 9 are constructed) would be anything other than a material that would facilitate penetration of ethylene oxide in order to sterilize the wrapped sponges 6.

As a third matter, the Examiner has not provided a rationale why a person of ordinary skill in the relevant art would be motivated to modify the syringe of Dischler with the cold sterilization method of Richter. The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. In view of the U.S. Supreme Court decision in KSR v. Teleflex, U.S. Patent Office training materials state, "A key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reasons why the claimed invention would have been obvious"[10]. Richter discloses a dispenser 4 which, by design, is a multi-use dispenser that could present a relatively high risk of cross-contamination from one user to a subsequent user. Richter does not teach or suggest cold-sterilizing a dispenser, as discussed above. Even if Richter taught or suggested cold-sterilizing a dispenser, which Applicant does not admit, the Examiner has failed to articulate a rationale why a skilled person would be motivated to apply the cold-sterilization process of a multi-use dispenser taught by Richter to the single-use device of Dischler which, in contrast to Richter's dispenser, poses no risk of cross-contamination to a subsequent user. Even if a skilled person *was* motivated to modify the "dispenser" of Dischler with the cold sterilization process of by Richter, which Applicant doesn't admit, one does not obtain all elements of any one of Applicant's claims 58-96, as discussed above.

[7] U.S. Patent No. 3,396,419; column 4, lines 14-19.
[8] *Ibid*; column 2, lines 22-26.
[9] *Ibid*; column 4, lines 21-22.
[10] KSR Training TC3700, slide 5; published at http://www.uspto.gov/

Accordingly, the Applicants respectfully request that the rejection under 35 U.S.C. 103(a) be withdrawn.

CONCLUSION

By setting forth the clear grounds of error, Appellants do not assert that these are the only errors that the Examiner has made, nor do Appellants waive any arguments that may be asserted in an Appeal Brief. Accordingly, Appellants reserve the right to present additional arguments in the Appeal Brief in relation to the independent and also the dependent claims.

Appellants respectfully request that the Panel review and reverse the final rejections of claims 58-96 in the above-identified application, and that a Panel Decision allowing the application on the existing claims be issued.

Respectfully submitted,

October 16, 2008
Date

By: Michael G. Williams
Michael G. Williams, Reg. No.: 61,990
Telephone No.: 651-736-7430

Office of Intellectual Property Counsel
3M Innovative Properties Company
Facsimile No.: 651-736-3833